Remarks

Objections to the Claims

Claims 2 and 3 are objected to because they recite non-elected disease species. Claim 3 is canceled. Claim 2 is amended to advance prosecution by deleting the non-elected species.

The Office Action pointed out that claim 26 needed to be renumbered because original claim 26 was canceled in the preliminary amendment. New claim 32 is the claim identified as claim 26 in the response filed June 13, 2007.

Please withdraw the objections.

Rejections of Claims 2, 3, and 26-31 Under 35 U.S.C. § 101 and § 112 ¶ 1

Claims 2, 3, and 26-31 stand rejected under 35 U.S.C. § 101 as lacking utility, with a corresponding rejection for lack of enablement under 35 U.S.C. § 112 ¶ 1. Claims 3 and 29-31 are canceled, and claim 26 is re-presented as claim 32. Applicants respectfully traverse the rejections of claims 2, 27, 28, and 32.

The Office Action contends that the claimed method is not supported by either a specific and substantial asserted utility or a well-established utility. Office Action at page 3. The specification needs to make only one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112. *Raytheon v. Roper*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown."). The specification makes such an assertion. The specification teaches that the FRPL2 protein can be used in screening methods to identify potential therapeutic compounds for cardiovascular disorders. *See, e.g.*, page 4, last paragraph; and page 57, lines 6-9. The

specification also provides evidence of the distribution of FPRL2 mRNA in cells and tissues of the cardiovascular system. See Example 2, Table 1. In light of the disclosed unexpectedly high expression of FPRL2 in cardiovascular tissue and the knowledge in the art discussed below, the skilled artisan would readily perceive that FPRL2 modulation could be useful in the treatment of cardiovascular disorders.

First, the skilled artisan knows that stimulation of FPRL2 activates heterotrimeric G proteins involving Gαq subunits leading to an increase of the intracellular calcium ion concentration, which then triggers downstream cellular events such as phospholipase C activation. See page 49, lines 19-22; page 2, lines 21-31; and page 1, lines 16-26. In the case of cardiovascular tissue, for example a cardiomyocyte or smooth muscle cell, the cellular event triggered by an increase of intracellular calcium ions in the contraction of cells directly involved in cardiovascular function. For example, contracting cardiomyocytes pump blood at a rate commensurate with the requirements of the metabolizing tissue (see page 55, lines 11-15). Thus, it is reasonable to think that modulating intracellular calcium ion concentrations in cardiomyocytes by, *e.g.*, by modulating FPRL2 activity, could modulate the pumping force of the heart.

Second, the skilled artisan knows that the cellular event triggered by an increase of intracellular calcium ions in a blood vessel is the contraction of smooth muscle cells defining the diameter of the vessel; that is, modulating the diameter of a vessel regulates blood flow through this vessel (see page 55, lines 19-22; and page 56, lines 4-8). Thus, it is reasonable to think that by modulating intracellular calcium ion concentrations in smooth muscle cells, for example by modulating FPRL2 activity, one could modulate the diameter of a vessel and hence the flow of blood through the vessel.

Unless there is reason to doubt the asserted utility, Applicants are entitled to a presumption that the asserted utility is sufficient to satisfy 35 U.S.C. § 101:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d 1380, 1391 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). Applicants do not have to provide evidence sufficient to establish that the specification's asserted utility for the disclosed protein is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 U.S.P.Q. 351, 354 (C.C.P.A. 1965). Rather, to overcome the presumption that Applicants' asserted utility is true, the U.S. Patent and Trademark Office must establish by a preponderance of the evidence that it is more likely than not that one of ordinary skill in the art would question the truth of the statement of utility. M.P.E.P. § 2107.2(III)(A). The Office Action has not provided such evidence.

The enablement rejection is based on the assertion that the claims lack patentable utility. As explained above, the U.S. Patent and Trademark Office has not met its burden of establishing a *prima facie* case that the claims lack patentable utility. The Office Action asserts no other reason why the claims are not enabled.

Please withdraw the rejections.

Rejection of Claims 2, 3, and 26-31 Under 35 U.S.C. § 112 ¶ 2

Claims 2, 3, and 26-31 stand rejected for several reasons under 35 U.S.C. § 112 ¶ 2 as indefinite. Claims 3 and 29-31 are canceled, and claim 26 is re-presented as claim 32. Applicants respectfully traverse the rejections of claims 2, 27, 28, and 32.

First, the Office Action contends the claimed methods are unclear without a correlation step. Office Action at page 4, last paragraph. Independent claim 2 is amended to recite determining the activity of said polypeptide in the presence of the test compound and to include an identifying step. The specification supports these amendments, for example, on page 39, line 6 through page 44, line 8.

Second, the Office Action contends it is unclear how a therapeutic agent can be identified in the presence of an antagonist of an FPRL2 polypeptide, as encompassed by claim 3. Office Action at page 4, last paragraph. To advance prosecution, claim 3 is canceled.

Finally, the Office Action contends that the term "FRPL2" is indefinite. Independent claim 2 has been amended to recite the full name of the polypeptide. The FRPL2 polypeptide was known in the prior art; see the references cited at page 4, lines 11-18 of the specification. The Court of Appeals for the Federal Circuit has held that an adequate written description of a gene which is well known in the art does not require a structural recitation either in the specification or in the claims. *See Capon v. Eshhar*, 418 F.3d 1349, 1360-61, 76 U.S.P.Q.2d 1078, 1087 (Fed. Cir. 2005) ("the Board erred in ruling that § 112 imposes a *per se* rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field."). Applying the same logic, a sequence identifier for a well-known protein should also not be required.

Please withdraw the rejection.

Respectfully submitted,

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